

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

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| In re: |) | Chapter 7 |
| |) | |
| AKORN HOLDING COMPANY LLC et. al., |) | Case No. 23-10253 (KBO) |
| |) | |
| Debtors. |) | (Jointly Administered) |
| |) | |
| |) | Hearing Date: May 30, 2023 at 11:00 AM |
| |) | Objection Date: May 16, 2023 |
| |) | |
| |) | Docket Nos. 106, 146, and 191 |
| |) | |

**DECLARATION IN SUPPORT OF
GALENICUM HEALTH, S.L.U.'S
RESERVATION OF RIGHTS AND LIMITED OBJECTION**

1. I, Joaquim Domingo on behalf of Matarrania Partners, S.L., managing director (*consejero delegado*), of Galenicum Health, Sociedad de Responsabilidad Limitada Unipersonal organized under the laws of the Kingdom of Spain (“Galenicum” or “Company”), hereby declare under penalty of perjury (“Declaration”):

2. Except as otherwise indicated, all facts set forth herein are based upon my personal knowledge of Galenicum’ operations and finances, information learned from my review of relevant documents, and information supplied to me by Galenicum’ personnel. I am authorized to submit this Declaration on behalf of Galenicum, and, if called upon to testify, I could and would testify competently to the facts set forth herein.

3. There is a License and Supply Agreement dated 22 December 2021 (“Contract”) between the above captioned debtor (“Debtor” or “Akorn”) and Galenicum. There is a cure amount of \$250,000.00 accrued, due, and owing under the Contract by the Debtor to Galenicum. The Trustee, however, has identified the Contract in the assumption notice with a cure amount of \$0, which demonstrates to the Company that it does not intend to pay any cure in violation of

11 U.S.C. §365(b)(1)(A). The Contract includes a license of technology which includes various trade secrets, scientific know-how, and confidential business information, which are not assignable absent Galenicum's consent under both the terms of the Contract and applicable law. Galenicum also further reserves its rights to further assert additional cure amounts related to multiple contractual covenants which Akorn had previously satisfied but the Trustee has not to date, as it has not communicated or consulted with Galenicum to date. To date, my counsel informs me that the Trustee has not filed a reply to the *Galenicum Health, S.L.U.'s Reservation of Rights and Objection to Cure and Assumption and Assignment* [Filed 5/16/2023; Docket No. 191].

4. The Contract contains various technologies, consisting of intellectual property and business information ("Technology") which is licensed by Galenicum to the Debtor. The Technology includes the following, which all has been shared with Akorn to date:

- Manufacturing process description of the product (including, how to keep sterile the product, how to reduce the particle size distribution in a consistent way, how to homogenize the suspension in order to get a homogeneous one, the method of obtaining an equivalent product to fluorometholone's reference listed drug).
- Formula description (including qualitative and quantitative components of the formulation, as well as batch size) also the quality of the excipients, and which plays a major role in the formulation.
- Packaging information details, including suppliers, materials of construction, sizes, etc.
- Excipients vendors and reference numbers.
- Active substance manufacturer.

- FDA dossier submission strategy. Confidential correspondence was held with the FDA and to define the strategy. All this information was also shared with Akorn.
- Manufacturer, type of equipment and configuration of the most critical equipment needed for manufacturing the product.
- Analytical results of Galenicum's development trials and prototype.
- Specification of the Active ingredient, finished product and packaging.
- Sterilization process. Since the product is not stable under the standard terminal sterilization conditions, a new specific and critical process was developed.
- How to select a manufacturing site, mainly which are the critical parameters to keep in mind in order to select the site. Information about the manufacturing site (including name, equipment, etc.).
- Contact information of Galenicum's technical personnel.
- Information about the development site, such as available equipment.
- Development details of the analytical method, as how to achieve discriminatory power of the dissolution test. Also, about the particle size distribution (regarding the comparability of the results between several techniques).

All the items listed above are all ***highly sensitive*** in terms of confidentiality and includes "know how" and trade secrets which if divulged would result in substantial harm to the Company.

5. Our Swiss counsel has advised me that the Contract is a personal services agreement that is not assignable under Swiss law, which is the governing law of the contract. I have been advised by counsel that under Swiss law the very nature of know-how license agreements prohibits any transfer of the license agreement by the licensee to a third party without the licensor's consent. There are three reasons for the restriction on assignment absent consent, as explained to me by Swiss counsel, all of which is material to Galenicum: (i) any

transfer potentially puts the confidential character of the licensed know-how at risk; (ii) know-how license agreements are concluded *intuitu personae*, because the licensor's trust in the specific licensee is an essential element of the agreement; and (iii) the assignee of the claim may be a competitor of the licensor, in which case the confidentiality and the entire business of the licensor may be in danger.

6. The licensing of the Technology and the ANDA rights, including the ANDA Dossier and related business and marketing information are the hallmarks of a personal services agreement and underscore the *intuitu personae* nature of the Contract, which cannot be assumed and assigned without Galenicum's permission under Swiss law. The Contract contemplates a close working agreement between the Debtor and Galenicum to protect its abbreviated new drug application ("ANDA") rights. Contract, Section 6.4. The Contract It contemplates that the parties would consult and notify each other regarding any regulatory activity that would affect Galenicum's ANDA rights. *Id.* at 6.5 and 6.6. The Debtors and Galenicum also are required to coordinate and notify each other regarding any product recalls. *Id.* at 6.7. Galenicum also has an obligation to facilitate and permit inspections of its manufacturing facility and open its facilities for the Debtor quality assurance representatives and for document review. *Id.* at 6.9. There are countless other examples of the integrated personal services nature of the obligations between the parties, including quality agreement requirements, pharmacovigilance agreements, reporting, books and records audits, and protections of trade secrets. *Id.* at 6.10, 6.11, Article 7, and 9.5.

7. The Contract obligations have been performed and are required to be performed in the future. During the term of the Contract to date, the parties have held frequent meetings, on a weekly basis, with the responsible people of Galenicum involved in the development of the product as well as the regulatory strategy. Critical and confidential project information was discussed in each of these meetings. By way of example, and this is not an exclusive list,


meetings were held between the parties on: 28/04/2022 12/05/2022 26/05/2022
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|------------|------------|------------|------------|------------|------------|------------|
| 10/06/2022 | 28/06/2022 | 07/07/2022 | 21/07 | 04/08 | 01/09/2022 | 15/09/2022 |
| 29/09/2022 | 13/10/2022 | 27/10/2022 | 10/11/2022 | 15/12/2022 | 12/1/2023 | |
| 19/1/2023 | 26/1/2023 | 2/2/2023 | 9/2/2023 | 16/2/2023 | 23/2/2023 | |

8. Galenicum also contracted with the Debtor because they are specialized in oftalmics products and in the type of services described in the Contract. This is a material aspect of the Contract.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 26, 2023



Name: Joaquim Domingo
Title: Managing Director (Consejero Delegado)
Matarrania Partners, S.L.,
Galenicum Health, Sociedad Limitada Unipersona